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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,454	10/04/2004	Hector Knight Castro	1483 WO/US	2287
7590 Tim A Cheatham Mallinckrodt Inc 675 McDonnell Boulevard PO Box 5840 St Louis, MO 63134			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 07/16/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,454

Applicant(s)

KNIGHT CASTRO ET AL.

Examiner

MELISSA PERREIRA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1,2 and 5-18 are pending in the application. Claims 6-15 are withdrawn from consideration and claim 4 was cancelled in the amendment filed 5/26/09. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 5/26/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1,2,5 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, 11/21/01) in view of Damhaut et al. (US 6,172,207B1) and further in view of Asai et al. (US 5,536,491) and evidenced by Stone-Elander et al. (5,308,944A) as stated in the office action mailed 2/25/09.
4. Applicant asserts that there is no evidence of record to support a conclusion that a sufficient showing has been made that the reference The Manual and Operating Instructions was actually disseminated. Applicant asserts that numerous situations are

conceivable that explain the existence of the document, but that do not support the conclusion that the document was actually disseminated, including for example:

5. a.) the document is a revision and Nuclear Interface GmbH internally decided not to provide the manual to customers because, for instance (i) the design of the dispensing unit was changed before the document was disseminated, or (ii) the manual had incorrect information
6. b.) the document is a revision and sales of the dispensing unit were discontinued before it was disseminated
7. c.) the document is an internal draft or a draft of a revision that was not disseminated before being further revised
8. d.) the document was fabricated by the third party who submitted it to the EPO and was never produced by Nuclear Interface GmbH.
9. Applicant further asserts that the office has failed to establish that any of the above scenarios did not occur, that the document was actually disseminated or that the document was not subject to a confidentiality agreement.
10. The assertions stated above are the opinion of the applicant, are based on hypothetical scenarios and are not based on any evidence. The applicant disclosed the Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, 11/21/01) in the IDS filed 12/4/06 under CFR 1.56 and thus declared that the reference is considered material that is pertinent to patentability.
11. In addition to being a manual for instrumentation which would be disseminated to those who utilize or purchase the FDG Synthesizer, the Manual and Operating

Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, also provides contact information including a phone number, fax number, website and information email address which shows that the manual was distributed those skilled in the art that would ultimately require company contact information.

12. Applicant asserts that if the autoclaving step of Asai et al. were substituted for the filtration step of Damhaut et al., in order to achieve purification and sterilization, the buffer would be added after autoclaving of the solution and that one of ordinary skill in the art would have to find some motivation to rearrange the steps of Damhaut et al.

13. The Manual and Operating Instructions was used to teach of the method of improving the stability (avoiding decomposition) of a FDG solution by adjusting the pH of the FDG solution to 5.5 with a buffered product prior to heating it to a temperature of 135 degrees (which encompasses the autoclave temperature of the instant invention as evidenced in the specification which teaches of an autoclave temperature of 134 degrees see specification, p4, line 1). The reference of Damhaut et al. was used to teach of a citrate buffered 18F-FDG solution for NMR. Therefore, it would have been obvious to one of ordinary skilled in the art to substitute the buffer of the Manual and Operating Instructions for the equivalent citrate buffer of Damhaut et al. as both are known to be used with FDG.

14. The reference of Asai et al. was used to teach that 19F-labeled MRI contrast agents are known to be sterilized by autoclave. Therefore at the time of the invention it would have been obvious to one ordinarily skilled in the art to autoclave a citrate buffered labeled FGD solution with predictable results, such as providing a sterilized

solution for the NMR/MRI imaging as the Manual and Operating Instructions teaches of heating a buffered FDG solution to a temperature of 135 degrees (which encompasses the autoclave temperature of the instant invention as evidenced in the specification which teaches of an autoclave temperature of 134 degrees see specification, p4, line 1).

15. Applicant asserts that Damhaut et al. teaches away from use of an autoclaving step, in that they disparage the use of process steps that require heating. Specifically, according to the abstract, the process of Damhaut et al. "is more rapid than conventional methods and is performed at room temperature rather than high temperature for conventional technology."

16. The reference of Damhaut et al. was not used to teach of autoclaving of the 18F-FDG solution but was used to teach of a citrate buffered 18F-FDG solution for NMR. Therefore it would have been obvious to one of ordinary skilled in the art to substitute the buffer of the Manual and Operating Instructions for the equivalent citrate buffer of Damhaut et al. as both are known to be used with FDG.

Conclusion

17. No claims are allowed at this time.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618